said hollow shaft for permitting a higher absorption rate of said bioabsorbable material of said flexible member.

27. (new) The tissue rivet of claim 19 in which said flexible member of the rear end has a smaller mass than the mass of said hollow shaft, whereby said flexible member at the rear end is absorbed prior to said hollow shaft so that the flexible member at the rear end does not separate from said hollow shaft.

REMARKS

The Examiner is thanked for the courtesy of the interview on February 21, 1995 with the Applicant and counsel. During the interview the claims of the patent that were in the Amendment After Final that was submitted in the parent application, but not entered, were discussed.

The claims filed in the FWC have been substituted with new claims 19-26. New independent claim 19 has added a preamble and clarifies that the flexible rear portion of the rivet is flexible enough so as to conform to the angle of the rivet to the tissue. This feature is not shown, taught or suggested by the prior art cited by the Examiner. The language of claim 19 has also been amended to recite that the projections are separate. No new matter has been added.

In addition, new claim 20, based on previous claim 11, has been amended such that preamble now more correctly recites that the claim is a combination claim. It is believed that as now amended, the objection to the claims and the specification under 35 U.S.C. § 112 have been overcome.

The language of claim 19 recites that the flexible member of the rivet is flexible so as to be able to deform and conform to the surface of the tissue in which the rivet is inserted as shown in Figure 4 of the Application. Such structure is not taught by Bays et al. The larger T-shaped head of the rivet of Bays et al. is not disclosed as being flexible so as to

be able to deform and conform to the surface of the tissue. The Bays head forms a sharp angle with the tissue, thereby creating a projection which could result in irritation in the tissues of the joint in which the tissues are being repaired. (See Col. 4, lines 20-28.)

The language of claim 19 has further been amended to recite the flexible projections as being separate from one another. This spacing in combination with the flexible structure of the projections allows the separate projections of the claimed invention to flex towards the shaft when being inserted in the tissue.

In contrast, Bays et al. teaches barbs that are not flexible since they are positioned adjacent to one another along the shaft as shown in Figures 2, 3, 5 and 6 and are incapable of flexing toward the shaft when inserted in tissue. As there is no space between the barbs of Bays et al., the barbs have no room to flex toward the shaft because the next in line barb will prevent the barb from flexing. Further, as can be seen in Figures 3 and 7 of Bays et al., showing a cross sectional view of the barbs, each of the barbs have a solid, wide attachment point along the longitudinal axis of the shaft. The wide attachment point of each barb in Bays et al. does not permit the projection of Bays et al. to flex so that they may be pushed through an opening that is smaller than the largest outside dimension of the projections. Instead, the barbs of Bays et al. have a tapered surface 18 "to facilitate the passage of the shaft portion 14 of the tack member 10 through cartilaginous or other tissue when the tack is moved forwardly (i.e. in the direction along the axis of the shaft position 14 and bone 13 from proximal end 11 toward distal end 12.)" (Col. 4, lines 37-42.)

The Bays et al. rivet is held in place by the projections, particularly the front projection which creates a hole in the tissue that is greater than the outside diameter of the remaining projections. The entire Bays et al. rivet has the potential of retreating out of the opening after its insertion.

The Bays et al. rivet will not work to fix soft tissue to soft tissue as the barbs would core out a path through the soft tissue or stretch the soft tissue to the same diameter of the barbs such that there would be no tissue left for the Bays et al. rivet to engage. In contrast, the projections of the rivet of the claimed invention do not increase the size of the opening in the tissue.

In further contradistinction, as recited in claim 19, the projections of the claimed invention are separate, flexible projections, flexing toward the shaft as they are pushed through a smaller opening in the tissue than the largest outside dimensions of the projections. In this manner, no path is cored out through soft tissue and the soft tissue is only minimally stretched. This is not taught, disclosed or suggested by Bays et al.

The recitation in claim 19 as to the flexibility of the projections is distinguished from the projections in Bays et al. The barbs of Bays et al. are not capable of flexing toward the shaft. The disclosure in Bays et al. cited by the Examiner that the barbs could be "semi-rigid" does not automatically suggest that the barbs would be flexible towards the shaft. "Semi-rigid" is a relative term such that the Bays et al. barbs could be "semi-rigid" compared to metal, but rigid compared to body tissue. Neither the disclosure nor the Figures of Bays et al. teach, disclose or suggest any use of the Bays et al. device that would permit the barbs to be flexible towards the shaft. The inflexible nature of the barbs of Bays et al. is most apparent in Figures 3 and 7 of showing a cross section of the barbs.

Moreover, there is no suggestion in Chisholm et al, that the projections of Chisholm et al. could be incorporated in the Bays et al. to form a medical rivet device. The Bays et al. device is a surgical rivet and specifically calls for rigid projections designed for a specific purpose, namely for meniscal repair. The Chisholm device is for a standard rivet that would be used in non-medical applications, such as in an automobile for fastening decorative trim to an automobile door interior. (col.

2, lines 25-26.) The Chisholm et al. device is not bioabsorbable and is not suitable for medical use in the human body. There is no teaching, disclosure or suggestion that the Chisholm et al. device could be used as a medical device to fasten tissue.

Even if the Chisholm et al. were to be reduced in size to be appropriately small for use in meniscal repair, it would not be insertable as it structure would be too weak due to its disporportionately large sized head relative to the shaft portion and barbs. There is no teaching, disclosure or suggestion in Chisholm et al, that if the Chisholm et al. device were to reduced in size, that the projections would be flexible toward the shaft when inserted in bodily tissue. In addition, the Chisholm et al. device does not have a hollow shaft to allow for the use of a driving means that is inserted in the hollow shaft for the insertion of the Chisholm et al. device. Further, there is no teaching or suggestion that the rear end of Chisholm be flexible so as to conform to an angle between the shaft and the rear end.

Further, the automotive rivet of Chisholm et al. is non-analogous art and certainly would serve no purpose in meniscal repair. As stated In Re Clay, 23 U.S.P.Q. 2d 1058 (Fed. Cir. 1992), the criteria for determining whether prior art is analogous has been developed over a period of years and includes the following elements:

> "1. Whether the art is from the same field of endeavor, regardless of the problem addressed, and,
>
> 2. If the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved."

The Court of Appeals in this case cited In Re Deminski, 796 F.2d 436, 432, 230 U.S.P.Q. 313, 315 and In Re Wood, 599 F.2d

1032, 1036, 202 U.S.P.Q. 171, 174.

Taking these elements into account, one must first look whether the art is from the same field of endeavor. It is respectfully noted, that the Chisholm et al. patent is directed to an automotive rivet which is not from the same field of endeavor as the medical rivet of the present invention.

With respect to the question of whether the "reference still is reasonably pertinent to the particular problem with which the inventor is involved", in fact the inventor of the present invention is not involved with automotive rivets for securing the trim to the interior of an automotive door, but rather is involved with the repair of the meniscus of a human face.

In an opposite vein, the question is whether a person using the automotive rivet as provided by Chisholm et al. would think of the automotive rivet as being useful for repairing the meniscus of a human knee. The Chisolm et al. rivet is for inert material wherein tissue viability is not a concern because it does not matter whether the inert material is stretched apart. In contrast, it is essential to tissue viability that the tissue not be overstretched or torn through. It is the flexible projections of the claimed invention which deform to limit the stretching of the tissue through which the rivet of the claimed invention is being inserted. Thus, injury to the tissue is kept at a minimum by the claimed invention. It is believed that the fields of Chisholm et al. and the field of the present invention are substantially remote from each other and that there would not be any overlap or thinking in the mind of a reasonable person that such would be considered analogous in the meaning of the Patent Statute.

For the reasons discussed above, it is not believed that the Chisholm et al. patent can reasonably be classified as "analogous art". Accordingly, it is believed that claim 19 presents novel and non obvious subject matter to overcome the rejections under 35 U.S.C. § 102(e) and § 103. As claims 20-27

are drawn dependent from claim 19, they are also believed to be allowable for the same reasons set forth above, in the discussion of claim 19.

In addition, claim 20 includes a driving means tip for a smooth transition from the tip of the driving means and the head of the rivet. The Examiner does not cite any portion of Bays et al. that teaches discloses or suggests such a feature in the rejection.

Claims 26 and 27 are directed to the flexible rear member. By having a smaller mass than the mass of the hollow shaft, the flexible rear member is bioabsorbed prior to the shaft and thus does not separate from the hollow shaft and fall into the wound, causing irritation and damage to the joint and tissues. This feature is inherent in the structure of the device as shown in the drawings and is not new matter. This feature is not taught or suggested by the prior art.

For the foregoing reasons, it is believed that all of the above claims are allowable over the prior art of record and that the Application is now in condition for allowance. A Notice of Allowance is requested.

Should the Examiner have any further questions, please contact the undersigned directly.

Respectfully submitted,

Dated: 3-17-95

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